

REMARKS

The Examiner's non-final Office Action of March 7, 2006, has been carefully considered. In the instant application, claims 1-9 are pending. Claims 3, 8 and 9 are withdrawn from consideration subject to a Restriction Requirement. Claims 1, 2 and 4-7 are rejected and objected. In view of the above amendment, and the remarks that follow, the reconsideration and withdrawal of the present basis for rejecting and objecting to the claims herein of this application is respectfully requested.

I. Discussion of the Amendment

Claim 1 is amended to limit R¹ being optionally substituted aryl, R² being optionally substituted oxazolyl, thiazolyl or pyrrolyl, and n being 1 or 3. Claim 1 is also amended to delete the proviso in the end of the claim in view of the amended definition of R².

Claim 3 is cancelled, without prejudice.

Claim 6 is amended to limit R² being optionally substituted oxazolyl, thiazolyl or pyrrolyl.

Claim 7 is amended to recite "a pharmaceutical composition" instead of "a pharmaceutical preparation".

Claims 7-9 are amended to be dependent upon claim 1.

Applicants reserve the right to pursue the cancelled subject matter of the claims in a subsequent application.

This amendment to the claims adds no new matter.

II. Discussion of the Priority

The present application claims the benefit of U.S. Provisional Application Serial No. 60/432,312, filed December 10, 2002 under 35 U.S.C. 119(e). Applicants claim priority under 35 U.S.C. 119 (a-d) to foreign application EPO 02017587.3, filed August 7, 2002. The Examiner asserts, however, that a certified copy of the foreign application has not been received.

Applicants respectfully submit that the certified copy of the foreign application EPO 02017587.3 was submitted to the Patent Office on August 7, 2003. A copy of the Application Transmittal Sheet (Exhibit A) is enclosed to evidence such submission. The submission is also evidenced by the electronic image of the priority document that appears in the Image File Wrapper of PAIR system.

III. Discussion of the Rejection on Claim 7 under 35 U.S.C. § 112, Second Paragraph

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants submit that claim 7 has been amended to recite "a pharmaceutical composition" instead of "a pharmaceutical preparation", thus, hereby obviating the instant rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection on claim 7 under 35 U.S.C. § 112, second paragraph.

IV. Discussion of the Rejection on Claims 1, 2, 4, 6 and 7 under 35 U.S.C. § 102(b)

Claims 1, 2, 4, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Atkinson et al. US Patent Pub. No. 2005/049237 (hereinafter the '237 publication). Specifically, the Examiner asserts that:

"The reference teaches the compound 1-(4-fluorophenyl)-N-(2-phenylcyclopropyl)-5-(trifluoromethyl)-1H-Pyrazole-4-carboxamide. The compound anticipates the compounds of formula (I) wherein n is 1, R¹ is an unsubstituted phenyl, R² is a 5 membered monocyclic heteroaryl containing two nitrogen atoms substituted by -CF₃, and phenyl; wherein the phenyl substituent on R² is further substituted by a halogen, namely fluorine. (See U.S. 2005/0049237 A1, p. 27, compound 310)"

See the Office Action, Page 8.

With the above amendment, Applicants respectfully traverse the instant rejection.

Applicants submit that claim 1 has been amended to limit R² being optionally substituted oxazoly, thiazoly or pyrrolyl. The amended claim 1 does not encompass compound 310 of the '237 publication, 1-(4-fluorophenyl)-N-(2-phenylcyclopropyl)-5-(trifluoromethyl)-1H-Pyrazole-4-carboxamide, corresponding to a compound of formula (I) wherein R² is pyrazolyl. Thus, the '237 publication does not anticipate the amended claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection on claim 1, and as well as claims 2, 4, 6 and 7 by virtue of their dependency on claim 1.

V. Discussion of the Rejection on Claims 1, 2, and 4-7 under 35 U.S.C. § 103(a)

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 103(a) as being obvious over the '237 publication.

With the above amendment, Applicants respectfully traverse the instant rejection.

Applicants submit that claim 1 has been amended to limit R² being optionally substituted oxazoly, thiazoly or pyrrolyl. The '237 publication teaches pyrazole amide compounds that correspond to compounds of formula (I) of the present application wherein R² is pyrazolyl. The '237 publication does not teach or suggest by any means compounds of formula (I) wherein R² is oxazoly, thiazoly or pyrrolyl. Thus, the '237 publication does not render the amended claim 1 obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant rejection on claim 1, and as well as claims 2, and 4-7 by virtue of their dependency on claim 1.

VI. Discussion of the Objection on Claims 1, 2, and 4-7 under 35 U.S.C. § 103(a)

a. Claim Objection-Non Elected Subject Matter

Claims 1, 2, and 4-7 are objected to as containing non-elected subject matter. The Examiner states "[T]o overcome this objection, Applicants should rewrite instant claims 1, 2, 4-7 deleting the nonelected subject matter and drawn only the examined elected subject matter." (See the Office Action, Page 12).

Specifically, the Examiner states in Section IV (B) (iii), entitled "Extended Prior Art Search
M.P.E.P. §803.02" that:

"The prior art search was extended to include the compounds of Formula (I)
wherein:

n is 1 or 3;

R¹ is an optionally substituted aryl;

R² is a 5 membered, monocyclic heteroaryl ring containing at least one nitrogen
which is optionally substituted by:

halogen, -CN, -NH₂, C₃-C₅-alkandiyl, phenyl, heteroaryl, aryl-substituted C₁-C₄-
alkyl, heteroaryl-substituted C₁-C₄-alkyl, -CF₃, -NO₂, -OH, phenoxy, benzyloxy,
(C₁-C₁₀-alkyl)-COO-, -S(O)_nR²⁰, -SH, phenylamino, benzylamino, (C₁-C₁₀-alkyl)-
CONH-, (C₁-C₁₀-alkyl)-CO-N(C₁-C₄-alkyl)-, phenyl-CONH-, phenyl-CO-N(C₁-
C₄-alkyl)-, heteroaryl-CONH-, heteroaryl-CO-N(C₁-C₄-alkyl)-, (C₁-C₁₀-alkyl)-CO-
, phenyl-CO-, heteroaryl-CO-, CF₃-CO-, -OCH₃O-, -OCF₃O-, -OCH₂CH₂O-, -
CH₂CH₂O-, -COOR²¹, -CONR²²R²³, -C(NH)-NH₂, -SO₂NR²⁴R²⁵, R²⁶SO₂NH-,
R²⁷SO₂N(C₁-C₆-alkyl)-."

See the Office Action, Pages 5-6.

Furthermore, the Examiner states in Section IV (B) (iii), entitled "Non-elected Subject Matter
Withdrawn 37 C.F.R. §1.142 (b)" that:

"The non-elected subject matter is the compounds of Formula (I) wherein:

n is 2 or 4;

R¹ is an optionally substituted heteroaryl;

R² is an optionally substituted aryl; a 5 member polycyclic or 5 membered monocyclic
or polycyclic heteroaryl containing heteroatoms consisting of O or S; an optionally
substituted 6-10 membered monocyclic or polycyclic heteroaryl ring; an optionally
substituted C1-C10 alkyl, optionally substituted C2-C10 alkenyl, optionally substituted
C2-C10 akynyl, optionally substituted C1-C10 alkoxy, optionally substituted akylamino,
optionally substituted di(C1-C10 alkyl)amino; a residue of a saturated or partially
unsaturated aliphatic monocyclic 5 to 7 membered optionally substituted heterocycle
containing 1, 2 or 3 heteroatoms selected from the group consisting of N, O and S."

See Office Action, Page 6.

Applicants respectfully point out that the Examiner has mistakenly understood the definition of
R² in claim 1. It is submitted that in the original claim 1, R² is defined as only being aryl or heteroaryl,
each of which is optionally substituted by the substituents listed therein. The groups cited by the
Examiner as part of the definition of R² being non-elected subject matter, i.e., "an optionally substituted
C1-C10 alkyl, optionally substituted C2-C10 alkenyl, optionally substituted C2-C10 akynyl, optionally
substituted C1-C10 alkoxy, optionally substituted akylamino, optionally substituted di(C1-C10
alkyl)amino and a residue of a saturated or partially unsaturated aliphatic monocyclic 5 to 7 membered
optionally substituted heterocycle containing 1, 2 or 3 heteroatoms selected from the group consisting of
N, O and S", actually are part of the list of substituents of the aryl or heteroaryl representing R², and are
not part of the definition of R² itself. For example, the elected species, Example 22, which is the starting
point of the Examiner's search, contains two alkyl (methyl) substituents on the corresponding R² ring, i.e.,
pyrrolyl. Claim 1 would not even encompass the elected species if the substituents of R² are only those
listed in Section IV (B) (iii) of the Office Action. Thus, Applicants submit that the aforesaid groups cited
by the Examiner should also be included in the list of substituents of R² being oxazoly, thiazoly or

pyrrolyl as elected subject matter. Applicants respectfully request the compounds resulting from these additional substituents of R² be searched and examined for the present application, if such were not encompassed by the search and examination already performed by the Examiner.

In addition, claim 1 has been amended to limit R¹ being optionally substituted aryl, R² being optionally substituted oxazolyl, thiazolyl or pyrrolyl, and n being 1 or 3. Thus, claim 1 only encompasses elected subject matter. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant objection on claim 1, and as well as claims 2, and 4-7 by virtue of their dependency on claim 1.

b. Dependent Claim Objections

Claims 2 and 4-6 are also objected as being dependent upon a rejected base claim.

Applicants submit that the present basis of rejecting claim 1, upon which claims 2 and 4-6 are dependent, is overcome by the above amendment. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant objection on claims 2 and 4-6.

Claim 7 is objected to because claim 7 recites "a pharmaceutical preparation", but actually claims a pharmaceutical composition.

Applicants submit that claim 7 has been amended to recite "a pharmaceutical composition" instead of "a pharmaceutical preparation", thus, hereby obviating the instant objection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant objection on claim 7.

VII. Conclusion

In view of the above remarks, Applicants respectfully submit that the present application is in condition for allowance. Early notice to this effect is, thus, respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. **18-1982** in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,



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Date: July 6, 2006

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sanofi-aventis Docket No.: DEAV2002-0058 US NP

EXHIBIT A

COPY

PATENT

UTILITY PATENT APPLICATION TRANSMITTAL

(only for new non-provisional applications under 37 CFR §1.53(b))

Mail Stop Patent Application
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing is the patent application
under 37 CFR 1.53(b) of:

AVENTIS DOCKET NO.: DEAV2002/0058 US NP
INVENTORS: STROBEL, et al.
TITLE: ACYLATED ARYLCYCLOALKYLAMINES
AND THEIR USE AS PHARMACEUTICALS

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Signature - Paul Irvine
EV 242704275 US
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APPLICATION ELEMENTS

1. ☒ *Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)

2. ☒ Specification
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

Total Pages 57

3. ☐ Drawing(s) (35 U.S.C. 113)

Total Sheets

4. Oath or Declaration

Total Pages 2

- a. ☒ Newly unexecuted (original or copy)
b. ☐ Copy from a prior application (37 CFR § 1.63(d))

- i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior
application, see 37 CFR §§ 1.63(d)(2) and 1.33(b).

5. ☐ Microfiche Computer Program (Appendix)

6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)

- a. ☐ Computer Readable Copy
b. ☐ Paper Copy (identical to computer copy)
c. ☐ Statement verifying identity of above copies

☐ If a **CONTINUING Application**, check appropriate box, and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part

of prior application no: _____, filed _____,

Examiner _____, Group/Art Unit _____.

(The cross reference has been/will be inserted on page one of the specification).

☒ This application claims the benefit of U.S. Provisional Application No. 60/432,312, filed December 10, 2002. (The cross reference has been/will be inserted on page one of the specification).

☒ This application claims the priority of European Application No. 02017587.3, filed August 7, 2002.

☒ **Incorporation By Reference** (useable if filing a continuation/divisional and a copy of the declaration from the prior application is enclosed.)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

ACCOMPANYING APPLICATION PARTS

7. ☐ Assignment Papers (cover sheet & document(s))
8. ☐ 37 CFR §3.73(b) Statement (when there is an assignee)
9. ☐ Verified English Translation Document (if applicable)
10. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
13. ☐ *Small Entity Statement(s) ☐ Statement filed in prior application, Status still proper and desired (PTO/SB/09-12)
14. ☒ Certified Copy of Priority Document – EP 02017587.3 (if foreign priority is claimed)
15. ☒ Other: Application Data Sheet

CORRESPONDENCE ADDRESS

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